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Food Safety Modernization Act Outreach Fall 2013 Session

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Approved By:
Scott Reynolds

Prepared By:
Darlene Dessureault

Report Highlights:
The United States Food and Drug Administration (FDA) held an outreach session with Canadian stakeholders on September 18, 2013 to get feedback on recently proposed rulemaking under the Food Safety Modernization Act (FSMA). This document outlines issues/areas of concern expressed by the Canadian industry stakeholders who participated, and the response from the FDA.

Food Safety Modernization Act Outreach Fall 2013 Session

Summary:

Representatives from the FDA, which included Deputy Commissioner for Foods and Veterinary Medicine Michael R Taylor, held an outreach session with Canadian food industry stakeholders on September 18, 2013 to answer questions regarding four proposed rules under the Food Safety Modernization Act (FSMA), as well as to seek feedback from industry. The four proposed rules were: (1) Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, (2) Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, (3) Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, and (4) Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications. Due to their impact on the proof that food imported into the United States will require, the Foreign Supplier Verification Programs (FSVP) rule and the Accreditation of Third Party Audits rule were the topics that generated the most questions from Canadian industry. Four main themes emerged from the sessions: (1) concerns over what was needed to ensure compliance, (2) impact that the rules may have on delays at the border, (3) what are the exemptions and why, and (4) the importance and desire for regulatory alignment. This document outlines issues/areas of concern for the proposed rules, as expressed by the Canadian industry stakeholders who participated, and the responses from the FDA.

Outreach Session:

1.) Compliance Requirements Related to FSVP and Foreign Accreditation Bodies/Program:

Canadian stakeholders sought clarification on whether existing accreditation bodies and auditors in Canada would be recognized, or if a new third party accreditation system was being proposed. Concerns were also expressed on the type of information the FDA would require to have confidence in the audit, and how the confidentiality of the information would be handled. The FDA representatives answered that a new program would be put in place, but that it will be based on current programs (international voluntary standards, as well as regulatory audits based on the Food Drug and Cosmetics Act, but not Codex or ISO) so Canada is well positioned for the transition. They added that the opportunities for further private/public partnerships are being explored. With regards to the audit information required, it was explained that the type of information included in the audit would include key food safety information including facility recall procedures, corrective actions taken etc., and stated that the information would become an FDA record and that the disclosure laws of such a record may be different in the Unites States than elsewhere.

Audit requirements for intra-company shipments that are going across the border were another area of query from Canadian stakeholders. The response was that the FDA was looking for input from stakeholders on this issue and, based on the input, would look into if modifications can be made.

Canadian industry also inquired on the scope of the audit's report (to whom an FDA accredited auditor would make the report to and what areas of the facilities would be subject to the audit). The short

answer was that it would depend on the audit. For example, the audit may be expanded to areas of the facility that was not producing export-destined product if there was a concern about cross-contamination.

2.) Impact on Border

Concerns over border delays were raised in relation to the Foreign Supplier Verification Program and Accreditation of Third Party Auditor's rules. The FDA representatives responded that no immediate effect on process and trade were anticipated and that only if there were violations would entry be prevented. They added that they will also be looking at how other agencies could potentially stop shipments, but cautioned that FDA can do very little for multi-jurisdictional products that may fall under other agencies (such as USDA) purview.

The question of how the FDA will address non-resident importers was also asked. The response from the FDA representatives was that Congress has decided that there needs to be an entity that the FDA can have jurisdiction over and, unfortunately, non-resident importers do not meet the requirements (needs to be a U.S. citizen). Canadian industry was encouraged to provide comments and propose solutions during the comment period that could address non-resident importers while respecting the bar set by Congress.

3.) Exemptions

Industry stakeholders asked for details regarding the "New Zealand exemption" and wanted to know if Canada could get one as well. Canadian stakeholders also showed interest in understanding the rationale for some of the proposed exemptions and modified requirements under the rulemaking (Tester exemption). Some concern was expressed by participants that the exclusions provided by the Tester exemption may negatively impact the food supply. Additional information was also requested of the FDA regarding the rationale behind the revenue exemptions, and why grain storage (at the farm level) is exempt.

From the outset, the FDA representatives made clear that no country "exemptions" were being given, however, if the system food safety system in the foreign country was comparable, then modifications were being considered in order to lighten the verification load for the importer. It was explained that Congress's decision is policy based, rather than science based, and that exemptions were provided by Congress with the intention of providing boundaries on federal regulation. The FDA clarified that only 10 percent of producers would be exempt from the standard, but that this did not mean that they were exempt from existing food safety provisions and state requirements. It was also made clear that the FDA reserved the right to pull "qualified (for exemption) facilities" back into the rule should a public health situation arise. On the issue of why on-farm storage is being exempt when potential health risks like microtoxins grow in storage, the explanation from the FDA was one of practicality. While statue dictates what to exempt, the decision is still logical as the grain usually goes into further distribution or processing so if there is a health risk, it will be caught further down the line.

4.) Regulatory Alignment

There were several questions related to efforts between Canada and the United States towards regulatory alignment, especially in light of the fact that Canada is addressing similar issues through its Canadian Food Safety Modernization efforts. In particular, one participant asked whether or not the FDA would consider aligning its concept of risk with that of the Codex and the Canadian Food Inspection Agency. The FDA representatives answered that a unified concept of risk is not possible due to the fact that it is used differently in different policy contexts. They went on to explain that their intent in developing the regulations was to align where possible and that a systems recognition approach was being worked on long before the RCC and FSMA. The FDA also cautioned industry that the agency is working on a judicially mandated deadline to have the rules in place by June 2015, but that Canada and the United States will continue to be in constant communication throughout the process. They added that since both countries are working on the same issues at the same time, so it has been very natural to work together.

The FDA representatives ended the outreach session by reminding Canadian industry participants how to make comments on the FSMA and the importance of submitting comments in writing. It was explained that comments must be registered in writing in order for the agency to be able to legally make changes to the rules. Canadian Industry expressed appreciation that the FDA held this outreach session. Comment periods on preventative controls and produce end on November 15, 2013, and comment periods for the FSVP and third party accreditation on November 26, 2013. Information on FSMA, including the text of the proposed rules, is available at: http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm